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C O N F I D E N T I A L SECTION 01 OF 02 TAIPEI 004160

SIPDIS

STATE FOR EAP/TC, ALSO PASS AIW/W

E.O. 12958: DECL: 10/12/2010

TAGS: AMED EIND TBIO TW

SUBJECT: TAIWAN MAY PRODUCE OSELTAMAVIR IF AVIAN INFLUENZA
BREAKS OUT

REF: TAIPEI 3742

Classified By: AIT DIRECTOR DOUGLAS PAAL FOR REASONS 1.5 (b) (d)

¶11. (C) Reftel reported on indications from senior officials that Taiwan may be capable of and intending to develop the ability to produce the anti-viral drug oseltamavir (trade name tamiflu), with or without permission from the patent holder, in the event of a breakout in Taiwan of human to human transmission of avian influenza (AI).

¶12. (U) According to an October 12 press report in the Liberty Times, Dr. Steven Kuo (shui-sung), Director of Taiwan's Center for Disease Control (TCDC) said that Taiwan should manufacture oseltamavir if avian influenza breaks out on Taiwan in order to protect the island's population. According to the press reports, Kuo said that Taiwan has the capability to produce the drug and should do so if needed whether patent holder Roche provides permission or not. Separate news reports on October 12 cite Taipei City Animal Control officials as warning the public not to have contact with live poultry because of the danger of avian influenza. Animal Control officials state that 14 Asian nations have been infected with AI and that now only South Korea, Japan and Taiwan are not infected.

Production Plans

¶13. (C) TCDC Director Kuo confirmed the news reports to AIT on October 12. He said that he had also given an interview to the New York Times on the same subject. Kuo went on to emphasize that Taiwan is struggling to strike an appropriate balance between the need to manufacture oseltamavir for national security needs and appropriate intellectual property rights protection. He noted that Taiwan's patent law provides for compulsory licensing, which also requires compensation be paid to the rightsholders. He confirmed that Taiwan has established a task force to examine the issues involved on both the technical and legal fronts. He said that both Roche and Gillette have claims on the rights to oseltamavir. According to Kuo, Taiwan now has drug stockpiles for less than 1% of the population and seeks to have sufficient dosages to treat 10% of the population. He said Taiwan now has contracts with Roche to supply by mid 2006 sufficient stocks to treat another 3-4% of the population. If Taiwan invokes compulsory licensing and produces its own supplies, Kuo said the goal would be to produce enough medicine to supply another 5% of the population. Thus, Taiwan would meet the WHO recommendation to have drug stockpiles to treat 10% of the total population.

In concluding his remarks, Dr. Kuo emphasized that to date, no Taiwan firm has started to produce the drug. He said that Taiwan is simply not yet at the point where it is ready to engage in discussions with Roche on the issue or to begin production. The raw materials for the drug would be imported from China. Kuo said that Taiwan has been importing the raw materials for many years and would only need to significantly increase its imports in order to be able to produce the oseltamavir.

Patent Law Provides for Compulsory Licensing

¶14. (U) Taiwan's patent law includes a compulsory licensing provision that officials could invoke to compel licensing authority from Roche to produce the drug in event of a declared emergency. Article 76 of Taiwan's patent law allows the Patent Authority to grant a right of compulsory licensing to satisfy domestic market requirements under three conditions: 1) national emergency; 2) non-profit use of a patent to enhance public welfare or 3) when an applicant has failed to reach a licensing agreement with the rights holder under reasonable commercial terms and conditions within a considerable period of time. Under Taiwan's patent law, Roche would receive "appropriate compensation" for the emergency use of its intellectual property. In case of a dispute over the amount of compensation, Taiwan's Patent Authority would determine the compensation. Taiwan's Intellectual Property Office confirmed to AIT/T the compulsory licensing provisions in its Law. To AIT/T's knowledge, this provision has only been used once and that was to secure licensing rights under provision number 3 above

in the information technology industry.

15. (C) Comment: We believe that Taiwan has been carefully planning how to increase its supply of oseltamavir and is prepared to invoke compulsory licensing provisions to achieve its goal of having sufficient stocks of the drug to treat 10% of its population. MOFA Vice Minister Kau Ying-mao assured the Director on October 12 that Taiwan is sensitive to this issue, and will work to accommodate the rightsholders. End Comment.

PAAL